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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,154	08/27/2001	John R. Bianchi	RTI-112RIA	5282

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,154

Applicant(s)

BIANCHI ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14, 30-44, 48-56, 60-83 and 85-89 is/are pending in the application.
- 4a) Of the above claim(s) 37, 38, 51, 52, 70 and 73 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 11-14, 30-36, 39-44, 48-50, 53-56, 60-69, 71, 72, 74-83 and 85-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>various</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 37, 38, 51, 52, 70, and 73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Elections were made **without** traverse in the replies filed on October 27, 2005 and August 20, 2004. To summarize, Applicants elected Group I (product claims), Species D (Figure 8), allograft (set 1), cortical bone (set 2), PLA (set 3), mineralized (set 4), block (set 5), tongue with groove (set 6), and pin or rod (set 7).

Drawings

The replacement drawing sheets were received on Feb 3, 2005. These drawings are approved.

The drawings are objected to because there is no legend under the drawings of the page 1 of the drawings indicating what drawing figure it is. Furthermore, Figures 31 to 34 do not have proper legends in that multiple figures are shown but not separately labeled with Figure numbers. Additionally, Figures 31 to 34 do not appear of good enough quality to be considered formal drawings that comply with Rule 84. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and

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where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

The specification contains serial numbers that are not updated with current patent numbers or current publication numbers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 70, 71, 72, 74, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 14, 70, 71, 72, 74, and 78, the transitional terms "comprising" are confusing since the implant components have already been set forth in

base claim 11. The Examiner suggests replacing the word "comprising" with "further comprising" in order to overcome this rejection.

With regard to claim 14, the multiple usages of the word "or" renders the claim indefinite because it makes it unclear where the alternative listing ends.

Claim Objections

Claim 77 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since claim 77 is merely a statement of intended use, it does not clearly modify the structure of the base claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40, 43, 44, and 49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 60 of copending Application No. 11/073202. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 40, 43, 44, and 49 are read on by the copending claim 60 in that the present claims are clearly obvious in view of claim 60.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40, 43, 44, and 49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 60 of copending Application No. 11/073400. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 40, 43, 44, and 49 are read on by the copending claim 60 in that the present claims are clearly obvious in view of claim 60.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Claims 40, 43, 44, and 49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 60 of copending Application No. 11/073281. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 40, 43, 44, and 49 are read on by the copending claim 60 in that the present claims are clearly obvious in view of claim 60.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 43 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27 and 31-34 of copending Application No. 09/782,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 43 is read on by the copending claims because it is sufficiently broad that all the limitations thereof are present in the copending claims. For this reason, it is considered to be clearly obvious in view thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 62 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Siebels et al (EP 0517030). Siebels anticipates the claim language where Siebels discloses an assembled bone implant made by assembling separate bone implant

pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation.

Claims 11, 12, 39, 43, 44, and 58 are rejected under 35 U.S.C. 102(b) as anticipated by Siebels et al (EP 0517030) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Siebels et al (EP 0517030) alone. Siebels anticipates the claim language because the cleaning process steps are viewed as product-by-process limitations that do not clearly alter the structure of the product; see MPEP 2113 that is incorporated herein by reference. In particular, the cleaning process steps do not clearly suggest a product that would be cleaner than that disclosed by Siebels.

Alternatively, one may view of the cleaning steps as having an effect on the final product structure. However, the Examiner asserts that any difference resulting from the process steps would at most result in only a slight difference between the claimed invention and the invention disclosed by Siebels. For this reason, the claimed invention is considered to be at least clearly obvious in view of Siebels alone.

Claims 14, 30-36, 40-42, 49, 50, 53-56, 60-61, 63-66, 68, 69, 71, 72, 74-80 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation. However, Siebels fails to

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disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6). Coates, however, teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner's position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels (EP 0517030) in view of Muller-Lierheim (US 4,828,563). Siebels meets or renders obvious all the claim language as set forth in the rejection of claim 11 *supra*, but fails to disclose the presence of a the bioactive agents set forth. However, Muller-Lierheim (see the abstract) teaches that it was known to coat similar implants in the art with growth factors. For this reason, it is the Examiner's position that it would have been obvious to coat the implant of Siebels with growth factors in order to reduce healing time at the implant site.

Claims 81-83 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Albee (article) or Brantigan (US 5,192,327) or Tienboon (US 5,861,041). Siebels meets the claim language except for the presence of the interlocking structures between the bone implant parts. However, Albee (see Figure 3 on page 179), Brantigan (see the figures) and Tienboon (see the figures) all teach that

it was known to include interlocking structures between adjacent bone implant pieces. Therefore, it is the Examiner's position that it would have been obvious to include interlocking features in the Siebels implant in order to better secure the implant portions to each other.

Claims 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels and Coates as applied to claim 14 above, and further in view of Albee (article), Brantigan (US 5,192,327) or Tienboon (US 5,861,041). Siebels meets the claim language except for the presence of the interlocking structures between the bone implant parts. However, Albee (see Figure 3 on page 179), Brantigan (see the figures) and Tienboon (see the figures) all teach that it was known to include interlocking structures between adjacent bone implant pieces. Therefore, it is the Examiner's position that it would have been obvious to include interlocking features in the Siebels implant in order to better secure the implant portions to each other.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Preblich whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

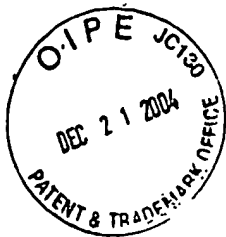
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738



ATTORNEY DOCKET NO. RTI 112R LA/1915/13980US03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:
John R. Bianchi, et al.

U.S. Serial No.: 09/941,154

Filed: August 27, 2001

For: "ASSEMBLED IMPLANT"

Previous Group Art Unit: 1615

Examiner: Paul B. Prebilic

CERTIFICATE OF MAILING

I hereby certify that this document and all documents referred to herein are being sent by first class mail, postage prepaid, to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

December 15, 2004

Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants

TRANSMITTAL OF 6 SHEETS OF SUBSTITUTE DRAWINGS

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants attach hereto six (6) sheets of Substitute Drawings (Sheets 3, 5, 6, 8, 9, and 10 of 14). The substitute sheets attached hereto remove all cross-hatching on FIGs 6-7, 13-14, 18, 20C, 21D, 21E and 22D as was requested in sister application USSN 09/782,594. No new matter has been added.

Should there be any fees involved in the filing of these drawings, please charge Deposit Account No. 13-0017.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By:

Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants
500 West Madison Street, 34th Floor
Chicago, Illinois 60661
(312) 775-8133

Date: December 15, 2004

Not
Approved
PBP
1-8-06

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE



In the Application of:
Bianchi, John R., *et al.*
Serial No.: 09/941,154
Filed: August 27, 2001
For: "Assembled Implant"
Group Art Unit: 3738
Examiner: Paul B. Prebille

CERTIFICATE OF MAILING

I hereby certify that this document and all documents referred to herein are being sent by first class mail, postage prepaid, to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

January 31, 2004

Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants

SECOND TRANSMITTAL
OF SUBSTITUTE DRAWINGS REQUESTED BY THE EXAMINER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Advisory Action of 01/04/05 in sister application USSN 09/782,594, wherein the Patent Office objected to the lack of cross-hatching in FIGs 6-7, 13-14, 18, 20C, 21D, 21E and 22D, Applicants attach hereto six (6) Substitute Sheets of Drawings (Sheets 3, 5, 6, 8, 9, and 10 /14) to be substituted for the originally filed Sheets 3, 5, 6, 8, 9, and 10 of 14.

The attached Substitute sheets of Drawings added appropriate cross-hatching to the cross-sectional drawings shown in FIGs 6-7, 13-14, 18, 20C, 21D, 21E and 22D. The appropriate cross hatching is as shown in the attached page of the MPEP at §608-02 for biochemical materials. No new matter has been added. Accordingly, this basis for objection to the drawings, as stated in the sister application, has been rendered moot.

Approved
for
entry
PPP
1-8-06